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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,303	10/07/2004	Kazunori Kataoka	2004-1437A	2024
513	7590	10/19/2005	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P.			HAQ, SHAFIQU	
2033 K STREET N. W.			ART UNIT	
SUITE 800			PAPER NUMBER	
WASHINGTON, DC 20006-1021			1641	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/507,303

Applicant(s)

KATAOKA ET AL.

Examiner

Shafiqul Haq

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Documents cited in IDS have not been considered because copies of those documents were not provided. In order to be in compliance with MPEP 609, III, A (2), applicants must provide copies of all of the references cited in the IDS. These references will become part of the official file of this application. Upon receipt of the missing documents, they will be considered by the examiner when preparing the next office action and a signed copy of form PTO-1449 will be provided with the next office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 5 is vague and indefinite because it is confusing as to what is meant by "the support of the surface".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being unpatentable by Lee et al. (US 6,235,340 B1).

Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language.

Lee et al. disclose a polymer composition (see Fig. 4 and column 12, lines 1-43 and column 13, lines 1-27) which anticipates polymer of general formula (I) of present invention. The polymer contains ethylene glycol (column 11, lines 54-67) and contains functional groups at either end (Z and W of general structure 1). Z may comprise trialkoxysilyl group (column 12, lines 25-30 and claims 19-21 and 48) for binding to surfaces and W represent other functional group (column 12, lines 49-52) which may bind to ligands (see fig. 4). The composition of Lee et al. is capable of performing applicant's intended use because Lee et al disclose that this composition can be used for biosensor (column 3, lines 32-53) and can be bonded to gold, copper and silver (column 19, lines 35-36). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide (CH₂CH₂O) repeat (i.e. value of "n") in the polymer are routine modifications in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

7. Claims 1-2, 5 and 7-8 are rejected under 35 U.S.C. 102(b) as being unpatentable by Ostuni et al. (Colloids and surfaces B: Biointerfaces 1999).

Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language.

Ostuni et al. disclose a polymer composition comprising a polymer represented by general formulas (I) (page 1) and formula (2) (page 9). The composition of Ostuni et al. is capable of performing applicant's intended use because Ostuni et al disclose that this composition can be bonded to gold and silver (Abstract and page 10, figs.A and B). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

8. Claims 1-3, 5, 7-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gitler et al. (5,204,239).

Gitler et al. disclose a polymer composition and biosensor chips wherein a polymer represented by formula (1) is absorbed or adsorbed onto the surface of the biosensor via the mercapto group present at on end of the polymer (Figure 2 and Example 2, bridging columns 9 and 10). Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language. Gitler et al also disclose method of preparation in which polymer is

attached to gold surface by contacting polymer micelles with gold surface (example 3). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

9. Claims 1-3, 5, 7-10 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Otsuka et al. (J. Am. Chem. Soc. 2001).

Otsuka et al. disclose heterobifunctional poly(ethylene glycol)(PEG) derivatives containing mercapto group at one end to couple with gold surface and a functional group at other end to couple to ligand (Abstract and pages 8226-8227 and scheme 2 of page 8228). Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language. Otsuka et al also disclose method of preparation in which polymer is attached to gold surface by contacting with gold surface (see synthesis of Au nanoparticles). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

10. Claims 1-3, 5, 7-10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kataoka et al. (US 2004/0038506 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Kataoka et al. disclose a polymer composition on surface of metal particle wherein a polymer represented by formula (1) is coupled onto the surface of the metal surface via the mercapto group present at one end of the polymer (Abstract and paragraphs [0015-0016] and [0045] and claims 1-2). The polymer of formula (1) anticipates formula (I) of claim 1 of present invention (Note that L1, L2= linker or bond). Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language. Regarding claim 5, Kataoka disclose gold particle, metal oxide, semiconductor (page 5, example 2 and paragraphs [0010, 0039, 0033, 0053]). Preparation in which polymer is attached to gold surface by contacting with gold surface is also disclosed (see examples 2 and 3). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

11. Claims 1-3, 5, 7-10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kataoka et al. (US 6,927,033 B2).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Kataoka et al. disclose polymer composition for forming surface of biosensor wherein a polymer represented by formula (I) is coupled onto the surface of the metal surface via the mercapto group present at one end of the polymer (Abstract and claims 1-4). The polymer of formula (I) anticipates formula (I) of claim 1 of present invention (Note that L1, L2= linker or bond). Regarding the claim language "it is a biosensor surface" in claim 1, it is the examiner's position that this is intended use language. Regarding claim 5, Kataoka disclose gold particle, metal oxide, semiconductor (see claim 2). Preparation in which polymer is attached to gold surface by contacting with gold surface is also disclosed (see example 1). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide (CH₂CH₂O) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,235,340 B1).

Lee et al. disclose polymer composition for coupling to biosensor as described in paragraph 6 above, but fail to disclose method of preparing surface containing the polymers.

Lee et al disclose surface containing the PEG containing polymer (see example 1) and contacting surface with polymer solution in the method of preparation of surface bound polymer is an obvious step in its production. Washing step and contacting (second time) is viewed as obvious optimization step which is routinely carried out to coat polymer to surfaces.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214

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USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/509,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because polymers of general formula (I) are the same as the polymer (I) of copending application. In the formula (I) of copending application, when $W^2\text{-PEG-W}^1\text{-L}$ is same in $(X\text{-}W^2\text{-PEG-W}^1\text{-L})_x$ and $(Y\text{-}W^2\text{-PEG-W}^1\text{-L})_y$, and when Y stands for functional moiety X, the polyethylene glycol (PEG) modified nanoparticle can be viewed as a nanoparticle surface linked with a PEG linker in which the other end of the linker has a functional moiety capable of binding to biomolecular target (note that W^1 and W^2 can be a single bond and L stands for linker or linkage portion). Copending application 10/509,576 disclose polymer composition having a mercapto group or trialkoxysilyl at one end and functional group or ligand at the other end. Preparation in which polymer is attached to gold surface by contacting with gold surface is also disclosed (see production examples 1-4 of pages 7-9). Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n")

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in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-3, 5 and 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,927,033 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because polymers of general formula (I) of present application are the same as the polymer (I) of copending application. Claims in the above patent disclose polymer composition containing functional group for coupling to biosensor surface and to ligands, which are same as the functional group of present application. Polymer chain number on surface (claims 1-2, 5) and the number of ethylene oxide ($\text{CH}_2\text{CH}_2\text{O}$) repeat (i.e. value of "n") in the polymer are routinely modification in the art for optimization and which have not been described as critical to the practice of the invention.

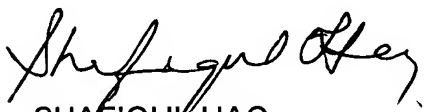
Conclusion

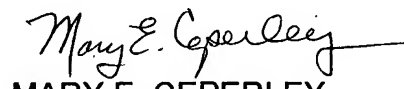
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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